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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/147,405      04/01/99      GUSS

B      REF/GUSS/P33

HM12/0427

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ALEXANDRIA VA 22314-1176

EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1645

18

DATE MAILED:

04/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/147,405

Applicant(s)  
Guss et al.

Examiner  
S. Devi, Ph.D.

Art Unit  
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on 02/28/01.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-29 ~~is/are~~ pending in the application.

4a) Of the above, claim(s) 2-24 and 26-29 ~~is/are~~ withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1 and 25 ~~is/are~~ rejected.

7) ☒ Claim(s) 1 and 25 ~~is/are~~ objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on Apr 1, 1999 is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other:

### **DETAILED ACTION**

#### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 02/28/2001 (paper no. 17) in response to the non-final Office Action mailed 10/03/00 (paper no. 16).

#### **Status of Claims**

- 2) Claims 1-29 are pending.

Claim 1 has been amended via the amendment filed 02/28/2001.

Claims 2-24 and 26-29 were withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Claims 1 and 25 are under examination.

#### **Priority**

- 3) It is noted that instant specification is a 371 of application PCT/SE97/01091, filed 06/18/1997, which claims foreign priority to application 9602496-3, filed in Sweden on 06/20/96.

#### **Prior Citation of Title 35 Sections**

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

#### **Prior Citation of References**

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

#### **Rejection(s) Withdrawn**

- 6) The rejection of claims 1 and 25 made by the previous Examiner in paragraph 5 of the Office Action mailed 10/03/00 (paper no. 16) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

#### **Rejection(s) Maintained**

- 7) The rejection of claims 1 and 25 made by the previous Examiner in paragraphs 7 and 8 of the Office Action mailed 10/03/00 (paper no. 16) under 35 U.S.C. § 102(b) as being anticipated by Timmerman *et al.* (*Infect. Immun.* 59: 4187-4192, 1991), is maintained for reasons set forth

therein and herebelow.

Applicants contend that Timmerman *et al.* disclose a 220 kDa protein antigen of *Staphylococcus epidermidis* which has adherence properties. Applicants state that Timmerman's protein cannot be the same as the protein of the present invention, because the molecular weight of the mature protein of the instant invention is "approximately 114 kDa" and that it has no significant plastic binding activity. Applicants further assert that there is no mentioning in the reference of Timmerman *et al.* that the protein has fibrinogen binding activity.

It is noted that the specification on page 16, lines 15-17 recite the molecular weight of the protein to be "approx. 100 kDa".

Applicants' arguments have been carefully considered, but are non-persuasive. First, instant claim 1, as drafted currently, is not limited to a *Staphylococcus epidermidis* protein having a molecular weight of approximately 114 kDa and insignificant fibrinogen binding activity. Claim 1 does not recite functional properties that distinguish it from Timmerman's protein. Furthermore, contrary to the Applicants' statement, Timmerman *et al.* disclose an approximately "100-110" kDa protein antigen of *Staphylococcus epidermidis* (see abstract) and thus reads on the instantly claimed protein. Since the prior art protein is structurally the same as the claimed protein, the fibrinogen-binding activity, not expressly stated by Timmerman *et al.*, is viewed as the inherent property of Timmerman's "approximately 110" kDa protein antigen of *Staphylococcus epidermidis*. The term "vaccine" in claim 25 is viewed as the intended use of the protein product and thus has no patentable weight. The rejection stands.

#### Objection(s)

Applicants' amendments made to claim 1 necessitated the following objections.

8) Claim 1 is objected to for the following reasons:

(a) Claim 1 is objected to for the incorrect recitation of "staphylococcus". To be consistent with the practice in the art, it is suggested that Applicants replace the recitation with --*Staphylococcus*--.

(b) Claim 1 is objected to for reciting a bacterial name, "staphylococcus epidermidis" without italicizing. To be consistent with the practice in the art, it is suggested that Applicants replace the recitation with --*Staphylococcus epidermidis*--.

(c) Claim 1 is objected to for lacking a preceding article before the recitation "Purified" (see line 1). It is suggested that Applicants change the recitation to --A purified--.

(d) Claim 25 is objected to for lacking a preceding article before the recitation "Vaccine" (see line 1). It is suggested that Applicants change the recitation to --A vaccine--.

9) The use of the trademarks in the instant specification has been noted in this application. For example, see page 7, line 12; page 13, line 25 recites "Tween 20". Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

10) It is noted that Figure 6 is improperly labeled. The sequence depicted in Figure 6 flows into next several pages. The first page of the drawing should be labeled as Figure 6A, and the second, third, fourth and fifth continuing pages as Figure 6B, 6C, 6D and 6E. The figure descriptions in the specification should refer to these sections as 6A, 6B, 6C, 6D and 6E. Reference to these Figures throughout the specification should be amended accordingly.

11) It is noted that the abstract of the disclosure contains legal phraseology such as "said", which should be avoided. Correction is required. See M.P.E.P 608.01(b).

#### **Remarks**

12) Claims 1 and 25 stand rejected.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week.

14) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday through Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would

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be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



S. Devi, Ph.D.  
Patent Examiner  
April 2001